

## § 822.4

of data or other information about a marketed device.

(i) *Prospective surveillance* means that the subjects are identified at the beginning of the surveillance and data or other information will be collected from that time forward (as opposed to retrospective surveillance).

(j) *Serious adverse health consequences* means any significant adverse experience related to a device, including device-related events that are life-threatening or that involve permanent or long-term injuries or illnesses.

(k) *Specific guidance* means guidance that provides information regarding postmarket surveillance for specific types or categories of devices or specific postmarket surveillance issues. This type of guidance may be used to supplement general guidance and may address such topics as the type of surveillance approach that is appropriate for the device and the postmarket surveillance question, sample size, or specific reporting requirements.

(l) *Surveillance question* means the issue or issues to be addressed by the postmarket surveillance.

(m) *Unforeseen adverse event* means any serious adverse health consequence that either is not addressed in the labeling of the device or occurs at a rate higher than anticipated.

### § 822.4 Does this part apply to me?

If we have ordered you to conduct postmarket surveillance of a medical device under section 522 of the act, this part applies to you. We have the authority to order postmarket surveillance of any class II or class III medical device, including a device reviewed under the licensing provisions of section 351 of the Public Health Service Act, that meets any of the following criteria:

(a) Failure of the device would be reasonably likely to have serious adverse health consequences;

(b) The device is intended to be implanted in the human body for more than 1 year; or

(c) The device is intended to be used to support or sustain life and to be used outside a user facility.

## 21 CFR Ch. I (4–1–10 Edition)

### Subpart B—Notification

#### § 822.5 How will I know if I must conduct postmarket surveillance?

We will send you a letter (the postmarket surveillance order) notifying you of the requirement to conduct postmarket surveillance. Before we send the order, or as part of the order, we may require that you submit information about your device that will allow us better to define the scope of a surveillance order. We will specify the device(s) subject to the surveillance order and the reason that we are requiring postmarket surveillance of the device under section 522 of the act. We will also provide you with any general or specific guidance that is available to help you develop your plan for conducting postmarket surveillance.

#### § 822.6 When will you notify me that I am required to conduct postmarket surveillance?

We will notify you as soon as we have determined that postmarket surveillance of your device is necessary, based on the identification of a surveillance question. This may occur during the review of a marketing application for your device, as your device goes to market, or after your device has been marketed for a period of time.

#### § 822.7 What should I do if I do not agree that postmarket surveillance is appropriate?

(a) If you do not agree with our decision to order postmarket surveillance for a particular device, you may request review of our decision by:

(1) Requesting a meeting with the Director, Office of Surveillance and Biometrics, who generally issues the order for postmarket surveillance;

(2) Seeking internal review of the order under § 10.75 of this chapter;

(3) Requesting an informal hearing under part 16 of this chapter; or

(4) Requesting review by the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.

(b) You may obtain guidance documents that discuss these mechanisms from the Center for Devices and Radiological Health's (CDRH's) Web site

(<http://www.fda.gov/cdrh/ombudsman/dispute.html>).

[67 FR 38887, June 6, 2002, as amended at 72 FR 17399, Apr. 9, 2007]

### Subpart C—Postmarket Surveillance Plan

#### § 822.8 When, where, and how must I submit my postmarket surveillance plan?

You must submit your plan to conduct postmarket surveillance within 30 days of the date you receive the postmarket surveillance order. For devices regulated by the Center for Devices and Radiological Health, send three copies of your submission to the Postmarket Surveillance Document Center (HFZ-541), Epidemiology Branch, Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229. For devices regulated by the Center for Biologics Evaluation and Research, send three copies of your submission to the Document Control Center (HFM-99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. For devices regulated by the Center for Drug Evaluation and Research, send three copies of your submission to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901-B Ammendale Rd., Beltsville, MD 20705-1266. When we receive your original submission, we will send you an acknowledgment letter identifying the unique document number assigned to your submission. You must use this number in any correspondence related to this submission.

[67 FR 38887, June 6, 2002, as amended at 70 FR 14986, Mar. 24, 2005; 73 FR 49942, Aug. 25, 2008]

#### § 822.9 What must I include in my submission?

Your submission must include the following:

- (a) Organizational/administrative information:
  - (1) Your name and address;
  - (2) Generic and trade names of your device;

- (3) Name and address of the contact person for the submission;

- (4) Premarket application/submission numbers for your device;

- (5) Table of contents identifying the page numbers for each section of the submission;

- (6) Description of the device (this may be incorporated by reference to the appropriate premarket application/submission);

- (7) Product codes and a list of all relevant model numbers; and

- (8) Indications for use and claims for the device;

- (b) Postmarket surveillance plan;

- (c) Designated person information;

- (1) Name, address, and telephone number; and

- (2) Experience and qualifications.

#### § 822.10 What must I include in my surveillance plan?

Your surveillance plan must include a discussion of:

- (a) The plan objective(s) addressing the surveillance question(s) identified in our order;

- (b) The subject of the study, e.g., patients, the device, animals;

- (c) The variables and endpoints that will be used to answer the surveillance question, e.g., clinical parameters or outcomes;

- (d) The surveillance approach or methodology to be used;

- (e) Sample size and units of observation;

- (f) The investigator agreement, if applicable;

- (g) Sources of data, e.g., hospital records;

- (h) The data collection plan and forms;

- (i) The consent document, if applicable;

- (j) Institutional Review Board information, if applicable;

- (k) The patient followup plan, if applicable;

- (l) The procedures for monitoring conduct and progress of the surveillance;

- (m) An estimate of the duration of surveillance;

- (n) All data analyses and statistical tests planned;

- (o) The content and timing of reports.